REMARKS

In accordance with the procedures set out in MPEP Section 708.02 (VIII), Applicant attended a personal interview with the Examiner on January 16, 1996, in an attempt to resolve all outstanding issues. It is believed that all outstanding issues regarding patentability have been resolved in view of the interview, the above amendments and the following remarks. Should the Examiner consider that any issues remain unresolved, Applicant respectfully requests that the Examiner contact the undersigned attorney by telephone so that such issues may be addressed promptly.

The Interview

On January 16, 1996, the inventor and the undersigned attorney attended an interview with Examiner Jordan at which all outstanding issues were discussed. With regard to rejection under 35 U.S.C. § 112, paragraph 1, it was agreed that these rejections would be overcome by an amendment to claim 67 which replaced the phrase "substantially free of EPA" with a numeric ratio by reciting that ARA:EPA was equal to or greater than 5:1. It was further agreed that the phrase "essentially free of EPA" in claim 70 was adequately supported in the Application as filed, *inter alia*, in passages incorporated by reference from Application Serial No. 07/645,454 and U.S. Patent No. 5,407,957. With regard to rejection under the judicially-created doctrine of obviousness-type double patenting, it was agreed that Applicant would supply a terminal disclaimer disclaiming any portion of the patent term which would extend beyond the term of parent U.S. Patent No. 5,374,657, once allowable claims have been agreed upon.

With regard to rejection under 35 U.S.C. § 103, Applicant pointed out that the present claims were directed to a particular subset of oil blends, the blends including one microbial oil and having particular properties (an amount of GLA which is converted in an infants body to the amount of

ARA comparable to the amount obtained from human breast milk or alternatively the amount of ARA sufficient to ensure that the ARA to EPA ratio is at least 5:1). While oils containing polyunsaturated fatty acids have been discussed in the literature, Applicant pointed out that there is no suggestion in the prior art to prepare or use the particular subset of oil blends recited in the present claims. The Examiner agreed to reconsider the present claims in view of the limitations on ARA:EPA ratio agreed to above.

The Amendments

The specification is amended to insert the application number of U.S. Application Serial No. 07/645,454 filed concurrently with the subject application and the patent number of U.S. Patent 45,407,957, which issued on U.S. Application Ser. No. 07/479,135. These amendments simply replace reference to applications which were identified in the application as originally filed with alternative serial and or patent numbers, and these numbers are characteristic of the applications referred to. Therefore, no new matter is inserted into the application by these amendments. The passage from U.S. Application Serial No. 07/645,454 inserted on page 7 of the present application was incorporated by reference at the time of filing, as indicated in a declaration by the inventor, Dr. David J. Kyle, dated July 2, 1994, and filed in the Parent Application U.S. Serial No. 07/944,739, now issued as U.S. Patent 5,374,657 (copy enclosed). Insertion of this material which was incorporated by reference in the application as filed does not introduce new matter into the subject application.

Claim 67 is amended to insert the definition of the term "substantially free" which was defined in Application Serial #07/645,454, on page 5, lines 12-14 ("'substantially free' means that the EPA is present in less than about 1/5 of the amount of ARA in the oil"), and incorporated by

reference into the subject application as originally filed (see also serial no. 07/645,454, page 8, lines 4-5: "preferably, the use of the ARA-containing oil will result in an ARA:EPA ratio of at least 5:1."). Claim 25 is amended as discussed at the interview to improve the clarity of the claim without any change in claim scope.

Applicants submit that the above amendments are fully supported in the subject application as filed and therefore add no new matter to the application. Applicants respectfully request that these amendments be entered in the application.

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 67-82 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the disclosure is enabling on for claims limited to composition where there is no limitation on the presence of EPA. Specifically, support for the phrases "substantially free" in claim 67 and "essentially free" in claim 70 are questioned. This rejection is respectfully traversed.

As discussed above, claim 67 is amended herein to provide a numeric ratio of ARA:EPA which represents the equivalent of the term "substantially free" as the term is used in claim 67. The preferred numeric ratio is fully discussed in the subject application as filed. The term "essentially free" as used in claim 70 means that the recited oils do not contain any significant quantity of EPA, and oils meeting this criteria are fully supported in the Parent Application as originally filed, particularly in passages of applications incorporated therein by reference. On page 7, lines 17-19, of Application Serial No. 07/645,454, incorporated into the subject application by reference, it is stated that "it is preferable to use species which do not produce significant quantities of EPA." U.S. Patent No. 5,407,957, in column 2, lines 8-10, states, "Preferably this oil will have no significant

quantities of other polyunsaturated fatty acids (PUFA's) i.e. greater than about 2% of the total fatty acid content," and, in another passage from this patent which was inserted the parent of the present application by amendment, it is stated that the desired fatty acid "is the only PUFA present in sufficient quantities (greater that about 1% of the total amount of PUFAs)."

Considering the subject application as a whole, including the passages incorporated by reference at the time the subject application was filed, claims 67 and 70, as well as claims dependent thereon, are enabled by the application as originally filed. Therefore, claim 67-82 are fully enabled based on the complete disclosure of the application as filed, including passages incorporated by reference, and Applicant respectfully requests that the rejection under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejection Under 35 U.S.C. § 112, Second Paragraph

This rejection is moot, as all of the rejected claims have been canceled.

Double Patenting Rejection

Pending claims 21-24, 36-39, 67-74, and 77-82 stand rejected under the judicially created doctrine of obviousness-type double patenting as unpatentable over claims 1-10 and 20-22 of U.S. Patent No. 5,374,657. Applicant respectfully requests that he be allowed to postpone responding to this rejection until claims are indicated to be otherwise allowable. At that time, Applicant proposes to overcome this rejection by submission of a terminal disclaimer as discussed in the Office Action, page 3.

Rejection Under 35 U.S.C. § 103

Claims 21-28, 36-42 and 67-82 stand rejected under 35 U.S.C. § 103 as unpatentable over Japanese Patent Application 196,255 and PCT Application WO89/00606 in view of Clandinin, et

al. U.S. Patent 4,670,285 and Traitler, et al., U.S. Patent 4,938,984. This rejection is respectfully traversed.

All of the cited references teach the use of oils containing polyunsaturated fatty acids (which may include DHA, EPA, ARA and GLA) in a variety of nutritional products including infant formula. However, none of the cited references teach or suggest blends of oils containing particular amounts of highly unsaturated fatty acids in ratios which fall within the scope of the amended claims. In particular, none of the cited references teach or suggest blends having high levels of DHA and either ARA or GLA while restricting EPA to very low levels. The presence of EPA in the diet can inhibit the production and/or metabolism of ARA (see, E.G. Carlson, et al., INFORM, 1:306 (1990), cited in the present application, page 1, line 21). However, Applicant was the first to recognize that such supplements could be prepared by blending a variety of oils including at least one microbial oil, thereby producing a supplement with high levels of DHA and either ARA or GLA without an accompanying detrimental level of EPA. None of the cited references suggest oil blends in which EPA is equal to or less than 1/5 the level of ARA for use in nutritional supplementation. The present claims are limited to such blends and may therefore be distinguished from the teachings of the cited references.

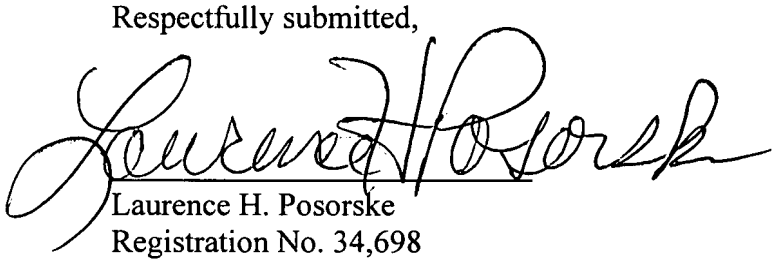
Applicant submits that references which are silent on the relative amount of EPA (WO89/00606 and Traitler et al.) or disclose formulations having ARA:EPA ratios on the order of 2:1 (JP196,255, examples 4 and 5) do not suggest the blends recited in the present claims. Clandinin, et al., does not suggest use of any microbial oil in infant formula, but only teaches the production of infant formula using egg yolk lipid or fish oil to produce an infant formula. The formula disclosed by Clandinin, et al using fish oil has an ARA:EPA ratio 1:15 (Table 7). Thus, no

combination of the cited references will suggest Applicant's invention, containing at least one microbial oil and having ARA:EPA ratio of at least 5:1.

Japanese Patent Application 196,255 and PCT Application WO89/00606 in view of Clandinin, et al. U.S. Patent 4,670,285 and Traitler, et al., U.S. Patent 4,938,984, taken alone or in any combination, do not teach or suggest the present invention. The invention claimed in amended claims 21-28, 36-42 and 67-82 is not obvious over the cited references, and Applicants therefore respectfully request that the rejection of these claims under 35 U.S.C. § 103 be withdrawn.

Applicants respectfully request reconsideration of the subject application in view of the above amendments and remarks.

Respectfully submitted,



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